REMARKS/ARGUMENTS

In response to the Office Action of May 28, 2004, Applicants request re-examination and reconsideration of this application for patent pursuant to 35 U.S.C. 132.

Claims 1, 39 and 44-46 have been amended. Claims 2-38 have been cancelled. Claims 39-46 have been withdrawn as a result of an earlier restriction requirement. Claims 1 and 39-46 remain pending in the instant application. Claim 1 is currently under examination.

No new matter has been added by the amendments to the specification. The title has been amended to more clearly indicate the invention to which the pending claims are drawn. The title has also been amended to correct a grammatical error (Alzheimers amended to correctly read Alzheimer's).

No new matter has been added by the amendment to claim 1. Claim 1 has been amended to indicate that the claimed biopolymer marker peptide is related to Alzheimer's disease. The instant specification discloses that such peptide is related to Alzheimer's disease at page 46, lines 10-19 and further discloses kits at page 47, lines 15-18. Claim 1 has also been amended to correct a grammatical error (Alzheimers amended to correctly read Alzheimer's).

No new matter has been added by the amendments to claims 39 and 44-46. These claims have been amended to correspond with claim 1 as amended herein.

Request for rejoining of claims under *Ochiai*

Applicants respectfully submit that the Examiner has misinterpreted the reference to the decision in *In re Ochiai* in the response filed on November 3, 2003. Applicants did not intend for this reference to be considered as an argument for withdrawal of the restriction requirement, but intended the reference to be a request to re-join claims 39-46 (withdrawn as being drawn to a non-elected invention) with the claim of the elected invention (claim 1) **upon the Examiner's determination that the claim of the elected invention is patentable** (page 11 of response filed November 3, 2003).

Rejection under 35 USC 112, first paragraph

Claim 1, as amended in the Response filed on November 3, 2003, remains rejected under 35 USC 112, first paragraph, as allegedly failing to comply with the enablement requirement for those reasons made of record in the previous Office Action mailed on July 29, 2003. The Examiner maintains the position that the instant specification, as originally filed, fails to provide any evidence or sound scientific reasoning that would support a conclusion that the claimed peptide (amino acid residues 2-14 of SEQ ID NO:1) could be used in the diagnosis of Alzheimer's disease with a reasonable expectation of success.

Applicants respectfully disagree with the Examiner's position.

The reference to MPEP 2165.03, at page 17 of the Response dated November 3, 2003, is misplaced and should not be construed to support the statement after which it is quoted.

The Examiner states that it is obvious that in order for a peptide to be indicative of a disease, a marker diagnostic for Alzheimer's disease, the peptide must be either present or absent or differentially expressed in Alzheimer's disease sample versus normal sample. The gel of Figure 1 provides an analysis of serum samples from Alzheimer's disease patients (AD, lanes 1-4) and serum samples from age-matched patients (control, lanes 5-8). The claimed peptide was isolated from each of the three bands distinctly labeled (C1, C2 and C3); however, as the gel shows, the claimed peptide appears to be strongly expressed in the serum from age-matched control patients as compared with expression in the serum from Alzheimer's disease patients. In other words, the gel shows a difference between two comparable serum samples. Thus, contrary to the Examiner's statement, the claimed peptide is shown to be differentially expressed in Alzheimer's disease sample versus normal sample.

The Examiner next asserts that the specification lacks a disclosure of a method of evaluation of the samples. Applicants respectfully disagree, and direct the Examiner's attention to specific sections of the instant application wherein such

disclosure regarding evaluation of the samples is provided, page 5, lines 12-22, page 26, lines 3-13 and page 47, lines 3-14.

The Examiner asserts that the Declaration of Jackowski under 37 CFR 1.132, filed on March 12, 2004, is insufficient to overcome rejection of claim 1 and further states that the Declaration provides more clarification on how the claimed peptide was discovered to be present in serum samples rather than enables the use of the claimed peptide for diagnosis of Alzheimer's disease. The Examiner asks if an unknown sample is presented for analysis and the sample is found to contain the claimed peptide, does this indicate the presence or absence of Alzheimer's disease?

The experiments disclosed in the instant specification establish spectra with regard to the claimed peptide which are intended to be used as reference points in a diagnostic assay. For example, the instant specification established spectra which show that the claimed peptide is more evidently expressed in the control serum versus Alzheimer's disease serum. These established spectra, which first indicated the claimed peptide was related to Alzheimer's disease, are identified as normal or diseased. When an unknown sample is presented for analysis, the spectra produced from the unknown sample is compared with the established spectra, both normal and diseased. If the claimed peptide is found in the unknown sample and appears to be strongly expressed in the unknown sample, similar to the expression established in the age-matched controls,

Alzheimer's disease is indicated to be absent.

The Examiner additionally indicates that there are a series of questions regarding the description of the samples used for analysis which remain unanswered. First in this series, the Examiner asserts that the specification, as filed, fails to present any description of the samples used in experiments to determine the presence or absence of the claimed marker. Applicants respectfully disagree. The "sample" is a sample obtained from a human patient (page 47,lines 4-6 and claims as originally filed). The "sample" is a body fluid, for example blood, blood products, cerebrospinal fluid (CSF), saliva, urine and lymph (preparatory protocols on pages 40-44 and page 49, lines 11-17). Additionally, Figures 1 and 4 show lanes labeled with individual patient identification numbers. Thus, samples used for analysis are described in the specification as filed.

The Examiner notes that there is no information in the specification regarding up or down regulation of the claimed peptide in serum samples of pathological conditions other than Alzheimer's disease. Applicants respectfully submit that no such information is required. The enablement requirement dictates that one skilled in the art must be enabled to make and use the invention that is **defined by the claims**. The peptide in claim 1 is not claimed to be related to any pathological condition other than Alzheimer's disease, thus such information regarding other

pathological conditions is not required in order to fulfill the requirement for enablement.

The Examiner further notes that the instant specification does not provide any information regarding serum samples of patients suspected of having Alzheimer's disease, in which the claimed peptide is present, followed up by a diagnosis of AD by using other diagnostic methods. Applicants respectfully submit that no such information is required. The intent of the instant invention is to provide an improved, alternative means for diagnosis of Alzheimer's disease. If "follow up" diagnostic methods are also required, then the diagnostic process is lengthened and the invention fails to fulfill its intended purpose. Thus, Applicants respectfully submit that if such information regarding other diagnostic methods was disclosed, it would actually teach away from enablement of the invention according to the intended purpose of the invention.

The Examiner concludes her arguments by asserting that the references presented in the Office Action mailed on July 29, 2003 which allegedly support the enablement rejection, still represent the state of the art in the field of diagnosis of Alzheimer's disease. Applicants respectfully submit that the cited references are not deemed to be persuasive enough to support the rejection.

The guidelines for a "test for enablement" indicate that if a statement of utility in the specification contains within it a connotation of how to use, 35 USC 112 is satisfied. Furthermore,

it has been established that the mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it. The instant application discloses a peptide (amino acid residues 2-14 of SEQ ID NO:1) which is related to Alzheimer's disease, such peptide has not previously been shown to be related to Alzheimer's disease. When a peptide is discovered to be associated with a disease state it carries with it a connotation of potential diagnostics and/or therapeutics. Thus, based upon the statements made in the instant paragraph, the cited references are not deemed sufficient to support an enablement rejection.

Although Applicants believe that the instant specification fully supports the claim that an isolated peptide consisting of amino acid residues 2-14 of SEQ ID NO:1 is diagnostic for Alzheimer's disease, in the interest of efficient prosecution Applicants have amended the claim(s) to recite that the isolated peptide is related to Alzheimer's disease.

According to dictionary.com the term "related" refers to the condition of being connected to or associated with something (see attached). The instant specification fully supports a connection and/or an association of the claimed peptide with Alzheimer's disease. The instant specification literally states, at page 46, lines 10-19, that the claimed peptide is related to Alzheimer's disease. The data presented in the figures, in particular, Figures

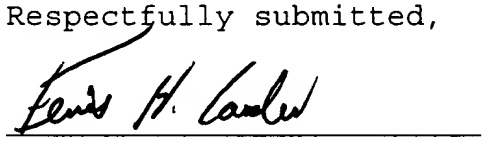
1, 2 and 4, further supports the association of the claimed peptide with Alzheimer's disease.

Accordingly, as demonstrated by the discussion presented above, Applicants assert that one of ordinary skill in the art when reviewing the instant specification and claims as amended herein would recognize that the isolated peptide consisting of amino acid residues 2-14 of SEQ ID NO:1 is related to Alzheimer's disease. Thus, Applicants respectfully request that this rejection now be withdrawn.

CONCLUSION

In light of the foregoing remarks and amendments to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested.

Respectfully submitted,



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re·lat·ed Pronunciation Key (rĭ-lā'tĭd)
adj.

1. Being connected; associated.
2. Connected by kinship, common origin, or marriage.
3. *Music.* Having a close harmonic connection.

re·lat'ed·ly *adv.*

re·lat'ed·ness *n.*

Source: *The American Heritage® Dictionary of the English Language, Fourth Edition*

re·late Pronunciation Key (rĭ-lāt')
v. **re·lat·ed, re·lat·ing, re·lates**
v. tr.

1. To narrate or tell. See Synonyms at describe.
2. To bring into or link in logical or natural association. See Synonyms at join.
3. To establish or demonstrate a connection between.

v. intr.

1. To have connection, relation, or reference: *The symbols relate to an earlier system.*
2. To have or establish a reciprocal relationship; interact: *She doesn't relate well to her peers.*
3. To react in response, especially favorably: *I just can't relate to these new fashions.*

[Obsolete French relater, from Old French, from Latin relātus, past participle of referre : re-, *re-* + lātus, *brought*; see tel₂- in Indo-European Roots.]

re·lat'a·ble *adj.*
re·lat'er *n.*

related

\Re*lat"ed\ (-l?t"?d), p. p. & a. 1. Allied by kindred; connected by blood or alliance, particularly by consanguinity; as, persons related in the first or second degree.

2. Standing in relation or connection; as, the electric and magnetic forcec are closely related.

3. Narrated; told.

4. (Mus.) Same as Relative, 4.

related

Relate \Re*late"\ (r?-l?t"), v. t. [imp. & p. p. Related; p. pr. & vb. n. Relating.] [F. relater to recount, LL. relatare, fr. L. relatus, used as p. p. of referre. See Elate, and cf. Refer.] 1. To bring back; to restore. [Obs.]

Abate your zealous haste, till morrow next again Both light of heaven and strength of men relate. --Spenser.

2. To refer; to ascribe, as to a source. [Obs. or R.]

3. To recount; to narrate; to tell over.

This heavy act with heavy heart relate. --Shak.

4. To ally by connection or kindred.

To relate one's self, to vent thoughts in words. [R.]

Syn: To tell; recite; narrate; recount; rehearse; report; detail; describe.

[Free Trial - Merriam-Webster Unabridged.]
Source: *Webster's Revised Unabridged Dictionary, © 1996, 1998 MICRA, Inc.*

related

adj 1: being connected or associated; "painting and the related arts"; "school-related activities"; "related to micelle formation is the...ability of detergent actives to congregate at oil-water interfaces" [syn: related to] [ant: unrelated] 2: connected by kinship, common origin, or marriage [ant: unrelated] 3: similar or related in quality or character; "a feeling akin to terror"; "kindred souls"; "the amateur is closely related to the collector" [syn: akin(p), kindred] 4: having close kinship and appropriateness; "he asks questions that are germane and central to the issue" [syn: germane(p)]

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related

related: in CancerWEB's On-line Medical Dictionary

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